

## EXHIBIT A

### PLAINTIFFS' ADDITIONAL PROPOSED JURY INSTRUCTIONS REGARDING "UNLAWFUL CONDUCT"

#### Unlawful Conduct - Dispensing

Plaintiffs contend that Defendants' conduct with respect to the dispensing of opioids was unlawful under the federal Controlled Substances Act – the CSA -- and under Ohio law.

It is unlawful for any person knowingly to dispense controlled substances other than in accordance with the requirements of the CSA and its implementing regulations, or in violation of the Ohio controlled substances laws and regulations.<sup>1</sup> Prescription opioids are controlled substances within the meaning of federal and Ohio law and regulations.

Under both federal and Ohio law, every entity that is authorized to dispense controlled substances is required to provide effective controls and procedures to guard against theft and diversion.<sup>2</sup>

In retail pharmacy stores, it is unlawful to dispense a controlled substance without a valid prescription.<sup>3</sup> A prescription, to be effective, must be issued for a legitimate medical purpose in the usual course of a professional practice.<sup>4</sup> An order purporting to be a prescription that does not meet this definition is not a "prescription" within the meaning of state and federal controlled substances laws, and it is a violation of those laws to knowingly fill such a purported prescription.<sup>5</sup> "Knowingly" in this context means a pharmacy may not fill a prescription that it knows or has reason to know is invalid and may not remain deliberately ignorant or willfully blind to the prescription information it has, including computerized reports and information it maintains. Employment of a pharmacist does not relieve a pharmacy or pharmacy owner of the obligation to ensure that only valid prescriptions are filled.<sup>6</sup>

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<sup>1</sup> 21 U.S.C. § 841(a); Ohio Rev. Code Ann. § 2925.03.

<sup>2</sup> 21 C.F.R. § 1301.71(a); Ohio Admin. Code 4729-9-05.

<sup>3</sup> 21 U.S.C.A. § 829.

<sup>4</sup> 21 C.F.R. § 1306.04.

<sup>5</sup> *Id.*

<sup>6</sup> Opinion and Order denying Defendants' motion to dismiss, Dkt. 3403 at 13-25; *see also Linden Med. Pharm. v. Ohio State Bd. of Pharm.*, 2001 Ohio App. LEXIS 2041, at \*24 (Ohio Ct. App. 11<sup>th</sup> Dist. May 8, 2001) (explaining that the Ohio Administrative Code "places

Pharmacies must “maintain systems, policies, or procedures to identify prescriptions that bear indicia (‘red flags’) that the prescription is invalid, or that the prescribed drugs may be diverted for illegitimate use.”<sup>7</sup> “Dispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances.”<sup>8</sup> Pharmacies also have an obligation under Ohio law to maintain adequate safeguards in their business to “allow[] pharmacists ... to practice pharmacy in a safe and effective manner.”<sup>9</sup>

If you find that the Defendants failed to comply with one or more of these duties in connection with their dispensing of opioids, then you may find that Defendants’ conduct with respect to dispensing was unlawful.

### **Unlawful Conduct – Distribution**

Plaintiffs also contend that Defendants’ conduct with respect to the distribution of opioids was unlawful under the federal Controlled Substances Act – the CSA -- and under Ohio law.

It is unlawful for any person knowingly to distribute controlled substances other than in accordance with the requirements of the CSA and its implementing regulations, or in violation of the Ohio controlled substances laws and regulations.<sup>10</sup> “Knowingly” in this context means only that Defendants were “conscious and aware” of their actions, “realized what [they were] doing or what was happening around [them],” and “did not [act] or [fail to act] because of ignorance, mistake, or accident.”<sup>11</sup>

The obligation to provide effective controls against diversion applies to distributors as well as dispensers of opioids.<sup>12</sup>

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the ultimate responsibility upon the ‘registrant’ ... to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs” and that “licensees electing to operate a business through employees are responsible to the licensing authority for their conduct”).

<sup>7</sup> Dkt. 3403 at 21-22 & 24-25.

<sup>8</sup> *Id.* at 24-25; O.R.C. § 4729.55(D). *See also* 21 C.F.R. § 1306.06 (“A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice . . .”).

<sup>9</sup> *Id.* at 20 & 24; O.R.C. § 4729.55(D).

<sup>10</sup> 21 U.S.C. § 841(a); Ohio Rev. Code Ann. § 2925.03.

<sup>11</sup> 1A Fed. Jury Prac. & Instr. § 17:04 (6th ed.).

<sup>12</sup> 21 C.F.R. § 1301.71(a); Ohio Admin. Code 4729-9-05; Ohio Admin. Code 4729-9-16(L);

Under both federal and Ohio law, wholesale distributors of prescription opioids, including the Defendants, have a legal duty: (1) to design and operate a system to identify suspicious orders; (2) to inform the DEA and Ohio Board of Pharmacy of suspicious orders when discovered; and (3) not to ship those orders unless investigation first shows them to be legitimate.<sup>13</sup> Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.<sup>14</sup>

If you find that the Defendants failed to comply with one or more of these duties in connection with their wholesale distribution of opioids, then you may find that Defendants' conduct with respect to distribution was unlawful.

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Ohio Admin. Code 4729-9-28(I).

<sup>13</sup> Opinion and Order Regarding Plaintiffs' Summary Judgment Motions Addressing the Controlled Substances Act, *In re: National Prescription Opiate Litig.*, 2019 WL 3917575, at \*7 & 9 (N.D. Ohio Aug. 19, 2019); Ohio Admin. Code 4729-9-16(H)(1)(e); Ohio Admin. Code 4729-9-28(E).

<sup>14</sup> 21 C.F.R. § 1301.74(b).